IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and DERMALOGIX PARTNERS, INC.,	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO. _____**
AKORN, INC. and VERSAPHARM INCORPORATED,	§	
Defendants.	§	

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, GALDERMA LABORATORIES, L.P., GALDERMA S.A. (together, "Galderma"), and DERMALOGIX PARTNERS, INC. (collectively, "Plaintiffs"), file this Original Complaint for Patent Infringement against Defendants AKORN, INC. and VERSAPHARM INCORPORATED (together, "Defendants") and state as follows:

PARTIES

1. Plaintiff Galderma Laboratories, L.P. ("Galderma L.P.") is a Texas limited partnership with its principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

2. Plaintiff Galderma S.A. is a Swiss company with its principal place of business at World Trade Center, Avenue de Gratta-Paille 2, 1018 Lausanne, Switzerland. Galderma S.A. and/or its affiliates are involved in the research, development, marketing, and sale of pharmaceutical products.

3. Plaintiff Dermalogix Partners, Inc. ("Dermalogix") is a Maine corporation with its principal place of business at U.S. Route 1, P.O. Box 1510, Scarborough, Maine 04074-9745.

4. Defendant Akorn, Inc. ("Akorn") is a corporation organized and existing under the laws of the State of Louisiana with its principal place of business at 1925 West Field Court, Suite 300, Lake Forest, Illinois, 60045, and may be served with process through its registered agent, Illinois Corporation C, at 801 Adlai Stevenson Drive, Springfield, Illinois, 62703.

5. Defendant VersaPharm Incorporated ("VersaPharm") is a corporation organized and existing under the laws of the State of Georgia with its principal place of business at 1775 West Oak Parkway, Suite 800, Marietta, Georgia, 30062, and may be served with process through its registered agent, Corporation Service Co., at 40 Technology Parkway, Suite 300, Norcross, Georgia, 30092.

JURISDICTION AND VENUE

6. This is a complaint for patent infringement. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

7. This Court has personal jurisdiction over Defendants because Defendants sell products for distribution throughout the United States and, on information and belief, regularly conduct business in the State of Texas. Defendants also submitted the ANDA (an act of infringement under 35 U.S.C. § 271(e)(2)) for the infringing product and issued a certification under 21 U.S.C. § 355(j)(2)(B) (the "Paragraph IV Certification")—the acts which give rise to the instant litigation—with knowledge that Galderma L.P. would be injured by such actions in this district, and delivered its Paragraph IV Certification Letter to Galderma L.P. in this district. Moreover, on information and belief, Defendants intend to sell the infringing product in or for distribution in this district upon approval by the FDA. Defendants have thus purposefully targeted their conduct to cause harm in the State of Texas and this district.

8. Venue is proper in this district because the claims asserted herein arise out of an act of patent infringement (*i.e.*, Defendants' submission of the ANDA and issuance of the Paragraph IV Certification) purposefully targeting a resident of this district (*i.e.*, Galderma L.P.). Further, venue is proper in this district because 21 U.S.C. § 355(j)(5)(C)(i)(II) establishes this district as the only proper venue in which Defendants could file suit seeking a declaration of non-infringement in connection with the ANDA.

BACKGROUND FACTS

A. The '920 Patent

9. On October 26, 1999, the United States Patent and Trademark Office issued U.S. Patent No. 5,972,920 (the "'920 patent"), entitled "Formulation Containing a Carrier, Active Ingredient, and Surfactant for Treating Skin Disorders," to Dermalogix Partners, Inc., the assignee of the named inventor William E. Seidel. Dermalogix is the current assignee of the '920 Patent.

10. Plaintiff Dermalogix granted Plaintiff Galderma an exclusive license to the '920 Patent to make, distribute, market, sell, and use a clobetasol propionate spray for the treatment of skin disorders including psoriasis. A copy of the '920 Patent is attached hereto as Exhibit A.

11. The '920 Patent is valid, enforceable, and has not expired.

B. Clobex® Spray

12. On October 27, 2005, the United States Food and Drug Administration (the "FDA") approved New Drug Application ("NDA") No. 21-835 for clobetasol propionate spray .05% for topical application. Galderma is the holder of NDA No. 21-835 for clobetasol propionate spray .05% for topical application, which Galderma sells under the name Clobex®.

13. The '920 Patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") as covering Clobex® clobetasol propionate spray .05% for topical application.

C. Defendants' Infringement

14. Defendants engage in the business of developing, manufacturing, and marketing generic pharmaceutical products.

15. Defendants reviewed the '920 Patent and certain commercial and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market clobetasol propionate spray 0.05%.

16. Defendants submitted ANDA No. 207218 seeking approval to engage in the commercial manufacture, use, and sale of generic clobetasol propionate spray 0.05% (the "Accused Product") prior to the expiration of the '920 Patent.

17. On or about February 29, 2016, Defendants sent a letter (the "Certification Letter") to Galderma L.P. in Fort Worth, Texas and to Dermalogix in Scarborough, Maine. Through the Certification Letter, Defendants first notified Plaintiffs that they had filed the ANDA with the FDA relating to the Accused Product and that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that, in Defendants' opinion, the claims of the '920 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of the Accused Product.

18. Defendants were aware of the '920 Patent when they filed the ANDA and/or sent the Paragraph IV Certification Letter.

19. Under applicable law, the Paragraph IV Certification Letter is required to include a detailed statement of the factual and legal basis of the opinion of the ANDA applicant

(Defendants) that the Accused Product will not infringe the '920 Patent. *See* 21 U.S.C. § 355(j)(2)(B)(iv). The Paragraph IV Certification Letter does not provide any explanation of Defendants' position regarding non-infringement of the '920 Patent.

20. The Paragraph IV Certification Letter was not accompanied by an offer of confidential access that would permit Plaintiffs access to the ANDA. After receiving the Paragraph IV Certification Letter, counsel for Galderma requested that Defendants grant Galderma confidential access to at least portions of the ANDA. When counsel for Galderma discussed gaining access to the ANDA with counsel for Defendants, counsel for Defendants told counsel for Galderma that Defendants had not provided an offer of confidential access because the Paragraph IV Certification Letter did not address non-infringement. To date, Defendants have refused to offer Plaintiffs access to the ANDA.

21. As a result, Plaintiffs do not have access to information that would allow Plaintiffs to confirm that Defendants' proposed generic version of Clobex® Spray is within the scope of one or more claims of the '920 Patent.

22. Plaintiffs are not aware of any other means of obtaining information regarding Defendants' proposed generic product. In the absence of such information, Plaintiffs must resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm infringement and to present to the Court evidence that Defendants' proposed generic version of Clobex® Spray falls within the scope of one or more claims of the '920 Patent.

23. Plaintiffs have commenced this action within 45 days of the date that they received Defendants' notice of the ANDA containing the Paragraph IV Certification Letter.

24. On information and belief, Defendants intend to continue seeking approval of the ANDA from the FDA, and to engage in the commercial manufacture, marketing, and sale of the Accused Product (including commercial marketing and sale of the Accused Product in the State of Texas, including this District), in the event that FDA approves the ANDA.

COUNT I:
INFRINGEMENT OF U.S. PATENT NO. 5,972,920

25. Plaintiffs incorporate the foregoing paragraphs by reference as if fully set forth herein.

26. The '920 Patent is valid, enforceable, and has not expired.

27. Defendants' submission of the ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of the Accused Product, prior to the expiration of the '920 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

28. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq.*, Defendants' ANDA must include information showing that the Accused Product (1) contains the same active ingredient as Clobex® Spray [21 U.S.C. § 355(j)(2)(A)(ii)(I)]; (2) has the same route of administration, dosage form, and strength as Clobex® Spray [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Clobex® Spray [21 U.S.C. § 355(j)(2)(A)(iv)].

29. As such, under 35 U.S.C. § 271(e)(2)(A), Defendants infringed the '920 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '920 Patent.

30. As a result of Defendants' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '920 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '920 Patent.

31. As a result of Defendants' infringement, pursuant to 35 U.S.C. § 271(e)(4)(A), Plaintiffs are entitled to an order that the effective date of any approval of the Accused Product described in the ANDA is not to be earlier than the date of the expiration of the '920 Patent including any patent extensions and any additional periods of exclusivity.

DEMAND FOR JURY TRIAL

In the event Defendants commercially manufacture, use, sell, offer to sell, or import the Accused Product prior to trial, Plaintiffs demand trial by jury of all issues and claims alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

(A) A declaration that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States of the Accused Product prior to the date of the expiration of the '920 Patent including any patent extensions, would constitute infringement of such patents in violation of Plaintiffs' patent rights;

(B) A declaration, pursuant to 35 U.S.C. § 271(e)(2)(A), that Defendants have infringed the '920 Patent by submitting the ANDA to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell in, or import into the United States, the Accused Product prior to the expiration of the '920 Patent, including any patent extensions, and that the Accused Product infringes such patents;

(C) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the Accused Product described in the ANDA is not to be earlier than the date of the expiration of the '920 Patent, including any patent extensions and any additional periods of exclusivity;

(D) An award to Plaintiffs, pursuant to 35 U.S.C. § 271(e)(4)(C), of damages and other monetary relief, as a result of Defendants' infringement, to the extent there has been any commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Accused Product prior to the date of the expiration of the '920 Patent, including any patent extensions and any additional periods of exclusivity; and

(E) Such other and further relief as this Court may deem just and proper.

Dated: April 14, 2016

Respectfully submitted,

/s/ Michael C. Wilson

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